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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,338	06/15/2005	Hartmut Juhl	411000-135	7356

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EXAMINER
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MACAULEY, SHERIDAN R

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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10/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/539,338

**Applicant(s)**

JUHL, HARTMUT

**Examiner**

Sheridan R. MacAuley

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/8/2005.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-15 are pending and examined on the merits in this office action.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kononen et al. (Nature Medicine, 1998, 4:844-847, cited in IDS) in view of Florell et al. (Mod. Pathol. 2001, 14:116-128). Claim 1 recites a method of creating a collection of isolated human tissue specimens, wherein each specimen is preserved after a defined period of time following isolation of the specimen from its natural environment and is then stored, and wherein the defined period of time between isolation and preservation of the various specimens is shorter than 25 minutes and shows a defined maximum deviation of not more than 10% of the defined period of time. Claim 2 recites the

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method of claim 1, characterized in that the condition of specimen following isolation thereof from its natural environment and prior to preservation thereof is recorded and documented. Claim 3 recites the method of claim 1, characterized in that the specimen has a defined volume. Claim 4 recites the method of claim 1, characterized in that said defined maximum deviation from said defined period of time is not more than 5%, based on said defined period of time. Claims 5-7 recite the method of claim 1, characterized in that said defined period of time is shorter than 15 minutes, 12 minutes, or 10 minutes. Claim 8 recites the method of claim 1, characterized in that preservation is effected by cryopreservation or by chemical preservation. Claims 9 and 10 recite the method of claim 8, characterized in that said chemical preservation involves the use of a crosslinking agent having reactive group, and that the crosslinking agent is selected from the group consisting of formaldehyde, polyaldehydes, polyepoxide compounds, and mixtures thereof. Claim 11 recites the method of claim 1, characterized in that said human tissue specimen is tumor-free tissue, tumor tissue and/or adipose tissue. Claim 12 recites the method 11, characterized in that said tumor tissue is central or peripheral tumor tissue. Claim 13 recites the method of claim 1, characterized in that data sets are assigned to the specimens. Claim 14 recites the method of 13, characterized in that said data sets contain information on the case history, medication, anesthesia, course of the operation, clinical parameters, and/or after-care data. Claim 15 recites a collection of human tissue specimens, containing isolated biological specimens that have been processed by the method of claim 1.

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4. Kononen teaches a method of creating a collection of isolated human tissue specimens (tumor specimens from tumor cores), wherein each isolated human tissue specimen is preserved (i.e. fixed) following isolation from its natural environment (p. 844, col. 2, par. 2, p. 845, fig. 1). In the method of Kononen, the specimens the human tissue specimen has a defined volume resulting from the use of thin-walled tubes and thin sectioning (see p. 845, fig. 1). The condition of the tissue specimen would have inherently been documented in the method of Kononen because the arrays prepared using the method can be used to survey a variety of tumor types and different stages of tumor progression (p. 846, col. 1, par. 1). The method of Kononen can be used with samples that have been preserved using formaldehyde (i.e. formalin; p. 846, col. 1, par. 3). Kononen teaches a collection of isolated human tissue obtained by the processes described therein (abstract). The eventual storage of the specimens and the collection of data related to each specimen would have been inherent to the method of Kononen.
5. Kononen does not specifically teach the use of a defined period of time with a defined standard deviation between the isolation and preservation of the tissues, specifically not a defined period of time with a value less than  $25\pm 10\%$ ,  $25\pm 5\%$ ,  $15\pm 10\%$ ,  $12\pm 10\%$  or  $10\pm 10\%$  minutes.
6. Florell teaches a method for the preservation of isolated human tissue specimens wherein each isolated human tissue specimen is preserved following isolation from its natural environment (abstract). Florell teaches that the RNA from surgical specimens is often degraded due to the variable amounts of time between the collection of the tissue and the preservation of the tissue (p. 117, col. 1, par. 1).

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7. At the time of the invention, a method for the preservation of isolated human tissue specimens comprising nearly all of the claimed elements was known, as taught by Kononen. It was further known that the preservation of tissues for RNA analysis is dependent upon the amount of time between the collection of the tissue and the preservation of the tissue, as taught by Florell. One of ordinary skill in the art would have been motivated to combine these teachings to develop a tissues collection method wherein the amount of time between the collection and preservation of the tissues is reduced and optimized because Florell teaches the desirability for the reduction of this amount of time and Kononen teaches that it is advantageous to fix tissues in a uniform manner (Kononen, p. 844, col. 2, par. 2). The selection of the claimed time periods and ranges would have been a matter of routine optimization for one of ordinary skill in the art, especially in the absence of evidence demonstrating the advantageousness of the specific time periods claimed. It would further be a routine matter of optimization for the a tissue collection to keep a corresponding data set for individual tissue specimens because Kononen discusses the use of the method for preparing microarrays to survey tissues from pathology laboratories (p. 846, col. 1, par. 1), which would have been catalogued with case histories of the patients from which the specimens were obtained. One of ordinary skill in the art would have had a reasonable expectation of success in combining the teaching discussed above because the claimed methods for preservation of isolated human tissue specimens were known in the art at the time of the invention, as taught by Kononen and Florell. It would therefore have been obvious to one of

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ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

8. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A Davis/

Primary Examiner, AU 1651